



CENTER FOR FOOD SAFETY

December 8, 2015

National Freedom of Information Officer
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

SUBMITTED VIA ONLINE SUBMISSION FORM

RE: Freedom of Information Act Request

To the National Freedom of Information Officer:

The Center for Food Safety (CFS) is a 501(c)(3) nonprofit organization that addresses the impacts of our current industrial food production system on human health, animal welfare, and the environment. Consistent with this mission and pursuant to 40 C.F.R. Part 2 and the Freedom of Information Act, 5 U.S.C. § 552, I, Ryan Berghoff, on behalf of CFS, respectfully request the following information:

1. **All documents relating to EPA's discovery that Dow AgroSciences made claims of "synergistic herbicidal weed control" in its provisional and non-provisional patent applications for Enlist Duo.¹**
2. **All documents relating to Dow AgroSciences provisional patent application for Enlist Duo filed on December 20, 2013, and the final application filed on December 11, 2014.²**
3. **All documents regarding the letter EPA sent Dow AgroSciences on October 13, 2015, requesting all available information that Dow had concerning "synergism."³**
4. **All correspondences concerning the synergistic effects mentioned in the provisional and non-provisional patent applications for Enlist Duo.**

"All documents" includes but is not limited to all correspondence, minutes, memoranda, communications, reports and/or other documents received from or given to applicants, or other governmental agencies, as well as maps, plans, drawings, emails, reports, databases, and phone notes. This request includes all documents that have ever been within your custody or control,

¹ See Respondent's Motion for Voluntary Vacatur and Remand at 5, *Natural Resource Defense Counsel v. United States Environmental Protection Agency*, No.14-73353 (9th Cir. Nov. 24, 2015) (Attached hereto as Exhibit A)

² *Id.*

³ *Id.* at 6

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whether they exist in agency "working," investigative, retired, electronic mail, or other files currently or at any other time.

CFS requests this information in light of the President's "Memorandum for the Heads of Executive Departments and Agencies" dated January 21, 2009, which states:

The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails...In responding to requests under the FOIA, executive branch agencies (agencies) should act promptly and in a spirit of cooperation, recognizing that such agencies are servants of the public. All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. The presumption of disclosure should be applied to all decisions involving FOIA. The presumption of disclosure also means that agencies should take affirmative steps to make information public.

Exec. Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 4,683 (Jan. 21, 2009). This request is being sent to the EPA FOIA officer with the understanding that it will be forwarded to other officers, offices, or departments with information pertinent to this request.

REQUEST FOR FEE-WAIVER

CFS requests that pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), EPA waive all fees in connection with the procurement of this information. As demonstrated below, the nature of this request meets the test for fee waiver as expressed in the Freedom of Information Act, 5 U.S.C. § 552(a)(4)(A)(iii).

The factors EPA must consider in deciding upon a fee waiver request are laid out in 40 C.F.R. § 2.107(l), and those relating to a significant contribution to public understanding of the operations or activities of the government can be summarized as follows:

- (1) Whether the subject matter of the request involves issues that will significantly contribute to the public understanding of the operations or activities of the Agency.
- (2) Whether the contents of the records to be disclosed have an informative value.
- (3) Whether the disclosure of the information will likely contribute to an understanding of the subject by the general public.
- (4) Whether the contribution to public understanding is significant.

40 C.F.R. § 2.107(l). These factors are to be balanced against one another; no one factor is determinative. See *Friends of the Coast Fork v. U.S. Dep't of Interior*, 110 F.3d 53, 55 (9th Cir. 1997).

The other requirements in the regulations—related to whether the requester has a commercial interest that outweighs a public interest motivation—are not applicable to CFS and this request. Under FOIA, a commercial interest is one that furthers a commercial, trade, or profit interest as those terms are commonly understood. *See, e.g.*, OMB Fee Guidelines, 52 Fed. Reg. 10017-18; *see also* 40 C.F.R. § 2.107(b)(1). Such interests are not present in this request. CFS does not seek information from EPA for commercial gain or interest. As a 501(c)(3) nonprofit organization, CFS has no commercial interest in EPA's involvement in the industry-led meeting of April 16, 2014.

In deciding whether the fee waiver criteria is satisfied, CFS respectfully reminds EPA that FOIA is inclined toward disclosure and that the fee waiver amendments were enacted to allow further disclosure to nonprofit, public interest organizations. *See* 132 Cong. Rec. S. 14270-01, (statement of Sen. Leahy) (“[A]gencies should not be allowed to use fees as an offensive weapon against requesters seeking access to Government information.”). Furthermore, the Ninth Circuit Court of Appeals has interpreted this fee waiver section broadly, holding that the section “is to be liberally construed in favor of waivers for noncommercial requesters.” *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1284 (9th Cir. 1987) (citing Sen. Leahy).

I. The present disclosure is in the public interest because it will significantly contribute to public understanding of the operations or activities of government.

The requested disclosure will contribute to public understanding of the operations or activities of the government. 5 U.S.C. § 552(a)(4)(A)(iii).

A. The subject of the disclosure concerns “the operations and activities of the government.”

The requested information pertains to EPA's proposed withdrawal of its approval of the herbicide Enlist Duo because of potential information regarding the potential adverse synergistic effects of the herbicide. Because the EPA is responsible for regulating the use of herbicides, this request regarding new information about the agency's subsequent withdrawal of its approval due to adverse synergistic effects relates to operations and activities of the government. This disclosure will demonstrate to the public at large how EPA regulates herbicides, as well as how the agency fulfills its duty to analyze potential synergistic effects of herbicides, which also directly relates to the operations and activities of the government.

B. The disclosure is “likely to contribute significantly to public understanding” of government operations or activities.

As discussed in the previous section, the present disclosure will provide the public a better understanding of how the EPA analyzes and decides whether to approve the use of herbicides in fulfillment of its regulatory duties. More specifically, the present disclosure will

provide the public with an understanding of how EPA analyzes the synergistic effects of ingredients when evaluating the safe use of an herbicide. It is essential for members of the public, including consumers and farmers, to understand how synergistic effects of ingredients in herbicides impact their safe use. It is also essential for members of the public, including consumers and other public interest organizations, to better understand how EPA reviews and evaluates claims of synergy in determining the safety of pesticides.

CFS is a non-profit organization that informs, educates and counsels the public—via legal action, our website, our True Food Network, books and reports, and our quarterly newsletter, Food Safety Now!—on the harm done to human health, animal welfare, and the environment by industrial agriculture. CFS, along with other national public interest organizations, submitted extensive comments on the proposed registration. Along with a group of national public interest organizations, CFS subsequently filed a lawsuit challenging EPA's registration of Enlist Duo. Accordingly, CFS is an effective vehicle to disseminate information on pesticides and genetically engineered crops, and specifically on EPA's review of the pesticide Enlist Duo, and their impact on human health, animal health, and the environment.

CFS regularly sends updates to its members concerning ongoing litigation, including its ongoing litigation challenging EPA's registration of Enlist Duo. When EPA rescinded its approval of Enlist Duo due to the new information concerning the potential synergistic effects of the two main ingredients in the herbicide, CFS posted a press release on its website and sent an email to its members regarding that decision. 4,470 people viewed the press release on the website and 65,093 people read the email. CFS intends to continue to update its members and the public-at-large regarding EPA's proposal to rescind the registration of Enlist Duo. Therefore, the information sought in the current FOIA request and its specific disclosure will contribute significantly to the public's understanding of how the synergistic effects of ingredients in an herbicide may result in the rescission of approval of an herbicide.

Simultaneously, this FOIA will help CFS fulfill its well established function of public oversight of government action. Public oversight of agency action in particular is a vital component in our democratic system and is the bedrock upon which the FOIA stands.

C. The disclosure will contribute to the understanding of a "reasonably broad audience of persons interested in the subject" (40 C.F.R. § 2.107(l)(2)(iii)).

EPA's approval of Enlist Duo is an issue of nationwide interest. EPA received more than 400,000 comments on the initial registration approval of Enlist Duo, and another additional 34,526 comments on the amended registration approval. EPA's decision to rescind the previous registration approvals are therefore of great interest to a broad audience of persons.

CFS is a member-oriented organization with over 700,000 members that works to address the impacts of the food system on human health, animal welfare, and the environment. Through over a decade of involvement in environmental litigation and policymaking as it relates to food,

CFS has demonstrated its ability to take technical information provided by government agencies and distill it into a format that is accessible to the public. CFS employs science and policy experts⁴ who have analyzed FOIA, NEPA, and other environmental and scientific reports for their entire careers. CFS puts out reports on pesticides, genetically engineered foods, food and feed additives, and other topics that tend to be difficult for the layperson to understand without professional assistance.⁵ CFS has made comments to EPA on the potential catastrophic effects of increased 2,4-D use due to new genetically engineered crop approval and the re-registration of the pesticide glyphosate. CFS also facilitates members' ability to confront agency inaction, such as the hundreds of thousands of citizens who petitioned EPA to act upon a CFS formal petition and adopt emergency measures to slow the spread of colony-collapse disorder in honey bees.⁶ CFS has also delivered to EPA a petition with over half a million signatures urging EPA to follow the European Union's lead in recognizing the risk of neonicotinoid pesticides.⁷ Finally, CFS regularly conveys information in accessible formats to its membership base through "Action Alerts" via email.

Federal courts have found that dissemination to 2,500 people through a newsletter and the intent to start a website is sufficient to meet the "reasonably broad audience" factor. *Forest Guardians v. U.S. Dep't of Interior*, 416 F.3d 1173, 1180 (10th Cir. 2005). Moreover, they have found that the proven ability to digest and disseminate highly technical information, as demonstrated by past analysis and dissemination, merits giving nonprofit organizations fee waivers. See *W. Watersheds Project v. Brown*, 318 F.Supp.2d 1036, 1040 (D. Idaho 2004). CFS's activity in these respects far outstrips any minimums established by judicial interpretation.

II. Obtaining the information is of no commercial interest to CFS.

The Center for Food Safety is a 501(c)(3) non-profit environmental advocacy organization that works to address the impacts of our food production system on human health, animal welfare and the environment. CFS works to achieve its goals through grassroots campaigns, public education, media outreach, and litigation. Under FOIA, a commercial interest is one that furthers a commercial, trade, or profit interest as those terms are commonly understood. See e.g., OMB Fee Guidelines, 52 Fed. Reg. 10017-18. Such interests are not present in this request. In no manner does CFS seek information from the EPA for commercial gain or interest. CFS respectfully files this FOIA request pursuant to its goal of educating the general public on the adverse effects of industrial agriculture. Upon request and free of charge, CFS will provide members of the public with relevant information obtained from EPA

⁴ See Leadership, Center for Food Safety, <http://www.centerforfoodsafety.org/staff> (last visited June 24, 2014).

⁵ See Publications & Resources, Center for Food Safety, <http://www.centerforfoodsafety.org/reports> (last visited June 24, 2014).

⁶ See Press Release, Center for Food Safety, 250,000+ to EPA: Time for Emergency Action on Pesticide to Protect Bees (June 28, 2012), <http://centerforfoodsafety.com/press-releases/713/250000-to-epa-time-for-emergency-action-on-pesticide-to-protect-bees>.

⁷ See Press Release, Center for Food Safety, Half a Million Demand Action from EPA to Save Bees (Mar. 21, 2014), <http://centerforfoodsafety.com/issues/304/pollinators-and-pesticides/press-releases/2995/half-a-million-demand-action-from-epa-to-save-bees>.

Based upon the foregoing, CFS requests that this FOIA be classified within the EPA's fee waiver category and that FDA send the requested information as required by law. As this is a matter of extreme importance to CFS, we look forward to your reply within twenty working days as required by FOIA. 5 U.S.C. § 552(a)(6)(A)(i). If the responsive records are voluminous please contact me to discuss the proper scope of the response. If any exemption from FOIA's disclosure requirement is claimed, please describe in writing the general nature of the document and the particular legal basis upon which the exemption is claimed. Should any document be redacted, please indicate the location of the redaction through the use of black ink.

Please provide any and all non-exempt portions of any document which may be partially exempt due to some privilege as required under *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973).

Please send all materials to the San Francisco address on the letterhead. Please call me at (415) 826-2770 if you have any further questions about this request. Thank you for your attention to this request.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Ryan Berghoff', is written over a horizontal line.

Ryan Berghoff
Legal Fellow
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Exhibit A

ORAL ARGUMENT NOT YET SCHEDULED
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE)	No. 14-73353
COUNCIL, INC.,)	
)	
<i>Petitioner,</i>)	
)	
v.)	
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY,)	
)	
<i>Respondent,</i>)	
)	
DOW AGROSCIENCES LLC,)	
)	
<i>Respondent-Intervenor.</i>)	

CENTER FOR FOOD SAFETY, <i>et al.</i>)	No. 14-73359
)	
<i>Petitioners,</i>)	
)	
v.)	
)	
UNITED STATES ENVIRONMENTAL)	
PROTECTION AGENCY, and GINA)	
MCCARTHY, in her official capacity)	
as Administrator,)	
)	
<i>Respondents,</i>)	
)	
DOW AGROSCIENCES LLC,)	
)	
<i>Respondent-Intervenor.</i>)	

**RESPONDENTS' MOTION FOR VOLUNTARY VACATUR AND
REMAND**

Respondent United States Environmental Protection Agency (“EPA”) hereby moves for voluntary vacatur and remand of EPA’s registration, as amended, of Dow AgroSciences’ (“Dow”) “Enlist Duo” herbicide under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). Enlist Duo is an herbicide developed for use on corn and soybean crops that are genetically engineered to be resistant to the two active ingredients in Enlist Duo. As explained below, because EPA is in receipt of new information regarding potential synergistic effects between the two ingredients on non-target plants, EPA seeks a voluntary remand in order to reconsider the Enlist Duo registration in light of the new information. EPA also seeks vacatur of the registration because EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA.

On November 24, 2015, Counsel for EPA informed counsel for all parties of EPA’s intention to file this motion. Counsel for Petitioners in these consolidated Petitions have indicated that their respective clients do not oppose this motion. Counsel for Dow has indicated that Dow intends to file a response to this motion.

BACKGROUND

FIFRA generally governs pesticide regulation in the United States. *See generally* 7 U.S.C. §§ 136-136y. It regulates the sale, distribution, labeling, and use of pesticides while protecting human health and the environment from associated unreasonable

adverse effects. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). To that end, FIFRA establishes a federal registration scheme that generally precludes distributing or selling any pesticide that has not been “registered” by EPA. 7 U.S.C. § 136a(a); *Fairhurst v. Hagener*, 422 F.3d 1146, 1151 (9th Cir. 2005). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used. *See* 7 U.S.C. §§ 136a(c)(1)(A)-(F), 136a(d)(1). Applicants for pesticide registrations must submit proposed label language addressing a number of different topics, including ingredients, directions for use, and adverse effects of the products. *See* 7 U.S.C. § 136a(c); 40 C.F.R. § 152.50 & Part 156. *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69, 71 (8th Cir. 1995).

FIFRA authorizes EPA to issue registrations for new active ingredients under section 3(c)(5) or “conditional” registrations under section 3(c)(7). 7 U.S.C. §§ 136a(c)(5), (c)(7). To support either type of registration, applicants must submit or cite studies intended to identify potential effects on human health and the environment. 7 U.S.C. § 136a(c); 40 C.F.R. Part 158. EPA approves each registration only after a careful review of the submitted product data and label. *See Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995). To register a pesticide under section 3(c)(5), as EPA did here, EPA must determine that (1) the pesticide’s composition warrants the proposed claims for it, (2) the pesticide’s labeling complies with the requirements of FIFRA, (3) the pesticide will perform its intended function

“without unreasonable adverse effects on the environment,” and (4) when used in accordance with widespread and commonly recognized practice, the pesticide “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5). As relevant here, the phrase “unreasonable adverse effects on the environment” is defined within FIFRA to mean “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide.” 7 U.S.C. § 136(bb)(1).

In November 2011, Dow applied to EPA for registration of Enlist Duo under FIFRA. ER 8. On October 15, 2014, EPA granted Dow’s request and issued a registration for Enlist Duo for use in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. *See* ER 7-8. Additionally, on March 31, 2015, EPA issued a final decision amending the registration to allow Enlist Duo use in Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. *See* ER 1-2. As part of the registration, EPA required certain drift reduction measures, including a 30-foot downwind in-field buffer from “sensitive areas” in order to avoid effects on non-target organisms, including endangered plant species, located off the field. ER 34-35. “Sensitive Areas” are defined by the label as any areas other than roads, paved, or gravel surfaces; planted agricultural fields (with the exception of certain crops susceptible to the herbicide); agricultural fields that have been prepared for planting; and areas covered by the footprint of a building, shade house, green

house, silo, feed crib, or other man-made structure with walls and or roof. *See* ER 498.

In response to comments contending that EPA did not address the potential synergistic effects of Enlist Duo's two active ingredients, EPA stated that it "adequately addressed the issue of synergism between [the two Enlist Duo ingredients] by evaluating data on the chemicals individually as well as with formulation-specific information." ER 19. After reviewing that information, EPA concluded that "[g]iven that there is no indication of synergism between [the two Enlist Duo ingredients] for mammals, freshwater fish, and freshwater invertebrates, EPA believes it is reasonable to assume that there are no synergistic interactions for the taxonomic groups that were not tested, including plants." *Id.* EPA also stated that "[t]he mixture [of the two ingredients] does not show a greater toxicity compared to either parent compound alone." ER 561.

Recently, however, EPA discovered that Dow made claims of "synergistic herbicidal weed control" in its Provisional and Non-provisional patent applications for Enlist Duo. The Provisional application was filed on December 20, 2013, and the final application was filed on December 11, 2014. *See* <http://portal.uspto.gov/pair/PublicPair> (Provisional App. No. 61919135; Non-provisional App. No. 14567574); Ex. 1 (October 13, 2015, Letter from EPA to Dow). On October 13, 2015, after reviewing the patent application, EPA sent Dow a letter

pursuant to 40 CFR §159.195(c) (implementing FIFRA section 6(a)(2), 7 U.S.C. § 136d(a)(2)), advising Dow that the claimed “synergism” could affect the Agency’s assessment of drift reduction measures for avoiding impacts to non-target organisms, including those listed as endangered, and requesting all available information within 30 days of the letter. *Id.* EPA received Dow’s response on November 9, 2015. EPA is still evaluating the extensive information contained in Dow’s response, but an initial review indicates that the 30-foot buffer included in the registration may not be adequate. Ex. 2 (Declaration of Donald Brady, Ph.D. ¶¶ 11-12.) Accordingly, in light of the new information regarding the potential synergism of the two Enlist Duo ingredients, EPA seeks a voluntary remand with vacatur to reconsider the Enlist Duo registration.

ARGUMENT

Agency decisions are not carved in stone. Instead, an agency must consider the “wisdom of its policy on a continuing basis,” for example, “in response to changed factual circumstances.” *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (citations omitted). “[W]hen an agency action is reviewed by the courts the agency may take one of five positions,” one of which is “seek[ing] a remand to reconsider its decision because of intervening events outside of the agency’s control” *SKF USA, Inc. v. United States*, 254 F.3d 1022, 1027-28 (Fed. Cir. 2001); *see also California Communities Against Toxics v. EPA*, 688 F.3d 989 (9th Cir.

2012) (citing *SKF*, 254 F.3d at 1029). Indeed, courts generally only “refuse voluntarily requested remand when the agency’s request is frivolous or made in bad faith.”

California Communities, 688 F.3d at 992. “Administrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts.” *B.J. Alan Co. v. ICC*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (quoting *Commonwealth of Pennsylvania v. ICC*, 590 F.2d 1187, 1194 (D.C. Cir. 1978)).

Here, EPA has learned that it did not have all relevant information at the time it made its registration decision. Specifically, Dow did not submit to EPA during the registration process the extensive information relating to potential synergism it cited to the Patent Office; EPA only learned of the existence of that information after the registrations were issued and only recently obtained the information. Ex. 2 (Brady Declaration ¶¶ 4, 5, 8). EPA’s scientists have preliminarily reviewed this data over the last two weeks, and believe, based on that review, that the data indicate that the 30-foot buffer on the approved label may not be adequate to protect non-target plant species located outside the treated fields. *Id.* ¶ 11. EPA requires additional time in which to fully assess the new information. *Id.* ¶ 12.

Because EPA has become aware of previously-existing information about possible synergistic effects that it did not consider, the Agency can no longer represent to the Court that its conclusions were correct regarding whether issuance

of the registration met the standard in FIFRA and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. EPA therefore consents to vacatur as well as remand of the Enlist Duo registration. Following remand and vacatur of the Enlist Duo registration, EPA would fully evaluate the new information and determine whether a new registration could be issued and, if so, whether additional terms and conditions would be necessary for the new registration.¹ To the extent that any interested party is not satisfied with any final action on remand, that party may obtain review of that agency action in this Court in accordance with FIFRA section 16, 7 U.S.C. § 136n.

In environmental cases, to decide whether remand with or without vacatur is the appropriate remedy, a factor this Court considers is the extent to which vacatur would cause or prevent possible environmental harm. *See Pollinator Stewardship Council v. EPA*, ___ F.3d ___, 2015 WL 7003600 at *12 (9th Cir. Nov. 12, 2015) (collecting cases). In *Pollinator Stewardship*, for example, this Court concluded that because of possible adverse effects on bee populations from the pesticide at issue in the

¹ In addition to its FIFRA-related concerns, EPA seeks vacatur and remand in light of the new information that came to light in Dow's patent application in order to review its determination that Enlist Duo would have no effect on species listed as endangered or threatened under the Endangered Species Act. In particular, EPA is concerned about the potential effects of Enlist Duo on certain plant species.

registration under review, “leaving the EPA’s registration . . . in place risks more potential environmental harm than vacating it.” *Id.* In light of that consideration, and because EPA could reach a different result on remand after obtaining the studies that the Court found were lacking, this Court vacated the registration. *Id.* A similar analysis applies here in that EPA may determine that changes to the registration are necessary to adequately protect non-target plant species, including those listed as endangered.

Specifically, before EPA can register a pesticide under FIFRA, FIFRA section 3(c)(5) requires that EPA determine, in part, that the pesticide “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D). EPA made such a finding here, supported by the 30-foot in-field buffer requirement. *See* ER 1, 8, 30, 34. However, the new information obtained from Dow calls that finding into question—the information suggests that EPA’s analysis may have understated the phytotoxicity of the product, therefore EPA can no longer be confident that Enlist Duo will not cause risks of concern to non-target organisms, including those listed as endangered, when used according to the approved label. Ex. 2 (Brady Declaration ¶¶ 10-12). And, based on the initial review of the new information, EPA believes that the 30-foot in-field buffer may not be adequate, thereby allowing a registration only on terms potentially different from those of the registration currently in effect. *Id.* Accordingly, keeping the registration in effect may

risk more environmental harm than vacating it, and it is possible that EPA's action on remand will result in a change to the registration.

A second factor courts consider in determining whether vacatur is appropriate is whether such relief (which constitutes an “interim change that may itself be changed”) would cause “disruptive consequences.” *California Communities*, 688 F.3d at 992 (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C.Cir. 1993)). While there may be some economic impacts to Dow from a vacatur, the extent of such impacts is unclear, and EPA believes that vacatur is appropriate in light of the potential environmental impacts and the fact that EPA's action on remand may result in a change to the registration. *See Pollinator Stewardship*, ___ F.3d ___, 2015 WL 7003600 at *12 (determining that vacatur is appropriate in light of potential environmental harm and fact that EPA may change registration on remand).

Thus, remand with vacatur is appropriate here. If this Court vacates this registration, EPA will then issue a cancellation order to regulate the sale, distribution, and use of existing stocks of Enlist Duo pursuant to FIFRA. *See* 7 U.S.C. § 136d(a)(1).

CONCLUSION

In summary, EPA has provided a reasonable basis for seeking voluntary remand. As the supporting EPA Declaration explains, the new information cited

above has called into question the validity of the Agency's earlier conclusion that use of Enlist Duo will not cause "unreasonable adverse effects on the environment."

Because remand with vacatur will be more protective of the environment and because EPA might not have issued the existing registration had it been aware of the potential synergy information at the time the initial registration was issued, vacatur is appropriate in this case. Thus, EPA respectfully requests that the Court vacate the Enlist Duo registration and to remand it to the Agency for further consideration.

DATED: November 24, 2015

Respectfully submitted,

JOHN C. CRUDEN
Assistant Attorney General
Environment and Natural Resources Division

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of RESPONDENT'S MOTION FOR VOLUNTARY VACATUR AND REMAND via Notice of Docket Activity by the Court's CM/ECF system, on November 24, 2015, on all counsel of record:

/s/ David A. Carson
David A. Carson